

Registration, Evaluation and Authorization of Chemicals (REACH) Directive

**Presented to the California Dep't. of Toxic Substances Control
by Todd O. Maiden**

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European Union



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European Union

- 25 countries
- population: 450 million
- produces 28% of world's chemicals
- 20% of all global imports and exports



Current Status of Chemical Regulations in the EU

- Abundance of laws: est. 40 Directives
- Perceived inconsistencies b\ t EU States
- Existing law based on “1981” baseline (“Existing” v. “new” chemicals)
- No testing for “existing” chemicals
- Test “new” chemicals as low as 10kg
- No incentive to create new chemicals



Primary EU Chemical Directives

- Classification and Labelling of Dangerous Substances (Directive 67/548/EEC)
- Classification and Labelling of Dangerous Preparations (Directive 88/379/EEC; revised by Directive 1999/45/EC)
- Evaluation and control of the risks of existing substances (Regulation (EEC) 793/93)
- Restrictions on the marketing and use of certain dangerous substances and preparations (Directive 76/769/EEC)



Perceived lack of information re Hi-volume chemicals:

- 65%: very little data (less than base set)
- 21%: no data
- 11%: minimum data (base set)
- 3%: adequately tested



Current System Unworkable

- public authorities currently in charge of assessing risks
- 100,106 pre-1981 (“existing” substances”)
- since 1993, 141 high vol. chemicals “prioritized”
- 70 substances finalized



EU Policy Objectives

- Protect public health and environment
- Maintain EU competitiveness (esp. SMEs)
- Stimulate innovation
- Fill regulatory gaps
 - (but streamline existing legislation)
- Establish common standards throughout EU



Underlying REACH Policy: The Precautionary Principle

1. when activity raises threats of harm
2. to human health or environment,
3. precautionary measures should be taken,
4. even if some cause and effect relationships are not fully understood

Shift burden to industry to “prove safe”

“Evaluation Goals”: More Data Sharing and Less Animal Testing

- Encourage Consortia
- Save money (SMEs)
- More innovation
- Ethical concerns
- Prefer *In Vitro* Testing





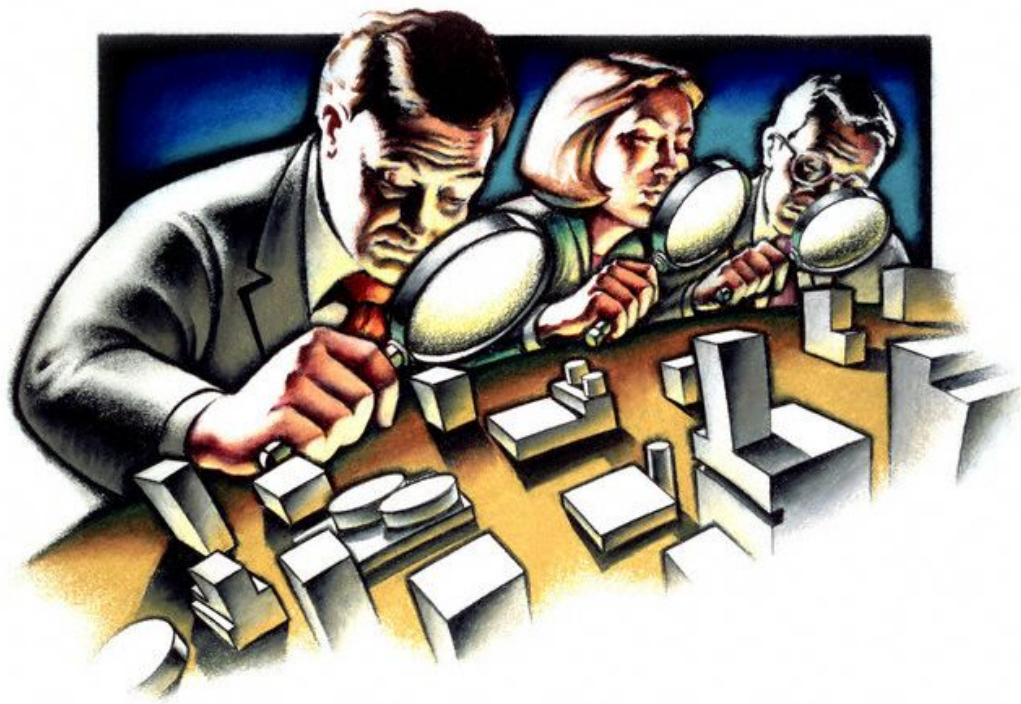
Substances of Very High Concern

- CMT's
 - carcinogens
 - mutagens
 - reproductive toxicants
- persistent, bio-accumulative and toxic substances (PBTs)
- very persistent and very bio-accumulative substances (vPvBs)

REGISTRATION OF SUBSTANCES



Evaluation



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REACH Authorization

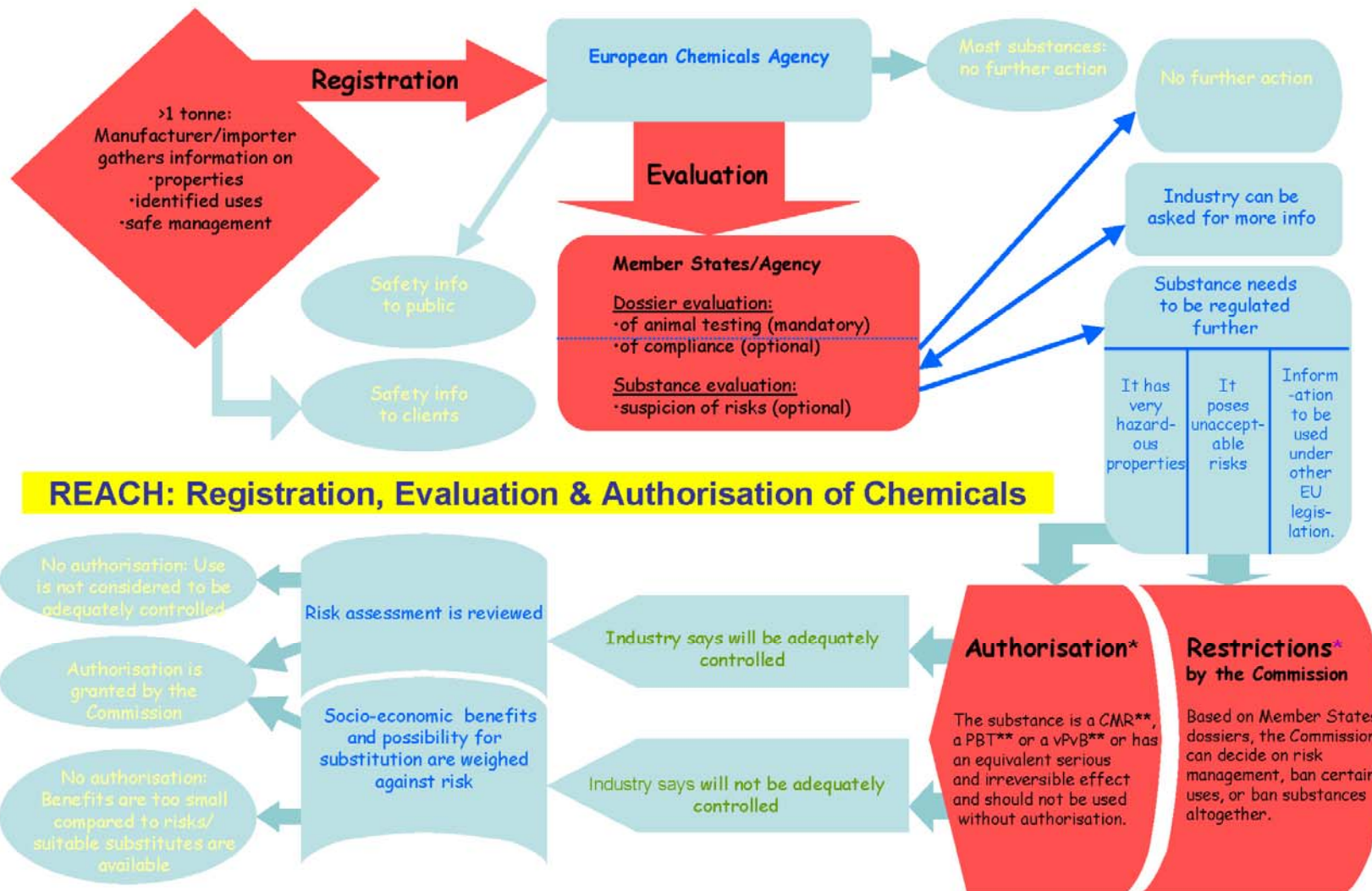


- based on Evaluation, Commission “authorizes” the manufacture, importation, distribution and \ or use of the chemical
- Policy: replace high hazard chemicals over authorization period



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* Substances do not have to be registered or evaluated to be placed under authorisation or restriction. They can be identified in other ways.

** Can cause cancer or mutations, or is toxic to reproduction; or is persistent, bio-accumulative and toxic, or very persistent and very bio-accumulative.

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REACH Implementation Projects (RIPs)

- RIP 1: Process Description
- RIP 2: REACH Information Technology
- RIP 3: Guidance for Industry
- RIP 4: Guidance for Authorities
- RIPs 5/6: European Chemicals Agency



RIP 1: REACH Process description

- Flowcharts
- Process Description



RIP 2: REACH Information Technology

- Dossier creation and management
- International **Uniform Chemical** Information Database (IUCLD v.5)
- **Non-confidential REACH data published** on public web-site
- European Chemicals Bureau



RIP 3: Guidance for Industry

- How to prepare dossiers
- How to conduct Chemical Safety Assessments
- Safety Data Sheet Guidance
- Info on intrinsic properties of substances
- Data sharing
- Downstream user requirements



RIP 3 (cont'd)

- Classification and labeling under [UN Global Harmonized System](#)
- Process for applying for:
 - authorizations for manufacture
 - use of prioritized substances of very high concern
- whether substances in articles require registration \ notification



RIP 3 (cont'd)

- when and how to conduct socio-economic analysis (SEA)
- Substance Identity:
 - characterization of substance
 - checking substance identity



RIP 4: Guidance for Authorities

- Dossier and substance evaluations
- Procedures for prioritizing substances for authorization (Annex XIII)
- Preparation of Annex XIV (re restricted substances – PBT and vPvB)
- Prioritizing substances for substance evaluation process



RIP 5/6: Establishment of the European Chemicals Agency

- 400+ employees by 2010
- Management Board
- Committee for Risk Assessment
- Committee for Socio-economic Analysis
- Member State Committee
- Forum for Exchange of Information on Enforcement
- Secretariat and Board of Appeal



Key Dates:

- 06/01/07: Effective Date
- April 2008: European Chemical Agency enters into operation



Pre-registration – April, 2008

- Prepare:
 - testing strategies
 - Chemical Safety Assessments
 - impacts downstream users who want to keep uses confidential
 - develop exposure scenarios for individual uses
 - < 1 tonne/yr exemption



Pre-registration - 2

- List of priority high risk chemicals
 - CMRs;
 - PBT: persistent, bioaccumulative and toxic
 - vPvB: very persistent & very bioaccumulative
 - est. 1,500?
- Substance Information Exchange Forums (SIEF)
- sharing animal test data



November 2010: Registration Deadline

- \geq 1000 tonnes/yr
- CMR \geq 1 tonne/yr
 - carcinogen, mutagen, reproductive toxin
- Aquatic toxicity (R50/53) and $>$ 100 tonnes/yr
 - Annex VII



Registration Deadlines - 2

- June 2013: 100-1000 tonnes/yr
- June 2018: \geq 1 tonne/yr

SO . . . What's not to like about REACH?



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The Good News

- Agreement with general objectives
- Acknowledgment of progress towards risk-based management
 - proportionate to volumes \ types
- Commitment to participation and achievement



Lingering Questions \ Concerns

- Implementation
- Adequate emphasis on risk based decision making
- Balancing objectives
- Cost effectiveness

Authorisation \ Substitution

- Authorize after showing of “adequate controls”
- Predict significant technical debates for CMRs, PBTs and vPvBs
- where adequate control not possible, authorize only if:
 - no safer alternative exists; and
 - socio-economic benefits outweigh risks





Substitution Issues

- “battle of the experts”
 - toxicologists
 - socio-economic (SEA) modelers
- extensive appeals
- agency bandwidth
 - Past: 70 “final reports”
 - Future: 1,500 approvals?



Confidentiality \ Data Protection

- sharing of data
 - efficiencies
- susceptible to unfair competition
- can request confidentiality on name
- incentive to innovate?
 - impact on low margin chemicals?
- future toxic tort claims?



Downstream Users

- separate filing for each anticipated use
- Capability / infrastructure?
- Articles provisions
 - whether enforceable \ workable in practice
 - information requirements



Consumer Information Provisions for Articles

- recognize public \ consumer right to know
- but need better balance with competing objective of commercially sensitive information
- adding consumer info obligations for articles may be duplicative – already covered by sector specific legislation



Standard of care

- prior: “duty of care”
 - differing interpretations within EU states
- replaced by “explanation of principles”
- impact on future claims / enforcement?



Workability

- Able to achieve objectives?
 - magnitude
 - complexity
 - aggressive deadlines
- “Sustainable development” test?
 - environment and human health
 - economically efficient
 - incentives

REACH Related Dispute Resolution

- Administrative appeals (authorisations)
- Toxic torts
- Intellectual property disputes
- Insurance coverage?



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Take Home Points

- EU fix for EU problem
- Laudable goals
- Optimistic? Aggressive? Naive?
- Precautionary Principle Experiment
- Questionable cost effectiveness
- Must comply, but anticipate “version 2.0”



Questions?

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